

REMARKS

This reply is fully responsive to the Office Action dated July 14, 2006, and is filed within five - (5) months following the mailing date of the Office Action. The Commissioner is authorized to treat this response as including a petition to extend the time period pursuant to 37 CFR 1.136(a) requesting an extension of time of the number of months necessary to make this response timely filed. The method of payment and fees for petition fee due in connection therewith is enclosed.

Interview Summary

10 On December 7, 2006, the Applicant and Applicant's representative held a telephonic interview with Examiner John Brusca. During the interview, the parties discussed Claim 1 and Caron et al. (hereinafter referred to as the "Caron reference"). Specifically, the Applicant contends that the Caron reference does not disclose "associating the gene expression within the first gene expression pattern with its corresponding exon," as required by Claim 1. The Examiner contends that in its broadest form, the Caron reference teaches such a limitation. However, the Examiner understood the Applicant's assertion that there is a difference between the present invention and the Caron reference and that if Claim 1 can be modified to further define those differences, then it may be possible that the claim overcomes the reference. No such amendment was
15 agreed to at that time.
20

On December 14, 2006, the Applicant's representative contacted Examiner John Brusca to further discuss Claim 1, the other independent claims, and the Caron reference. The Applicant proposed amending each independent limitation to include the following
25 language, "...associating the gene expression within the first gene expression pattern with its corresponding exon, the corresponding exon having a length such that the gene expression is associated with the entire length of the corresponding exon." The Examiner indicated that the amendment appears to differentiate the present invention from the Caron reference and would likely overcome the Caron reference. Therefore, each of the

independent claims, Claims 1, 20, 39, 58, 66, and 74 have been amended as described above and discussed with the Examiner.

Disclosure/Claims Status Summary:

5 The Examiner stated that the Office Action is in response to the communication filed on May 9, 2006. Claims 1-81 are pending in this application. More specifically, Claims 5, 6, 24, 25, 43, 44, 60, 68, and 76 are withdraw from consideration; Claims 1-4, 9-23, 28-42, 47-59, 62,-67, 70-75, and 78-81 were rejected; and Claims 7, 8, 26, 27, 45, 46, 61, 69, and 77 were objected to.

10

A. Claims Objections

The Examiner objected to Claim 81 under 37 CFR 1.75(c), as being of improper dependent form. The Examiner further stated that the Applicant is required to cancel the claim, amend the claim to place the claim in proper dependent form, or rewrite the claim
15 in independent form. For purposes of examination, the Examiner assumed the claim to depend from Claim 74.

Claim 81 has been amended to depend from Claim 80. Because this amendment is not considered to be narrowing and was therefore not made for statutory reasons of
20 patentability, the proposed amendment should not affect the doctrine of equivalents, as Festo should not apply. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 520 U.S. 1111 (1997).

As Claim 81 is now in a proper dependent form, the Applicant respectfully
25 requests that the Examiner withdraw this objection.

B. Claim Rejections – 35 U.S.C. §112

Claims 37, 55, 70-73, and 81 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

5

More specifically, the Examiner stated that Claims 37, 55, and 70-73, recite the limitations “an apparatus as set forth in Claim 11,” “a computer program product as set forth in Claim 1,” “an apparatus as set forth in Claim 58,” “an apparatus as set forth in Claim 62,” “an apparatus as set forth in Claim 6,” and “an apparatus as set forth in Claim 10 64,” respectively. The Examiner also stated that there is insufficient antecedent basis for this limitation in the claims. The Examiner continued by stating that the rejection would be overcome by amending Claims 37, 55, and 70-73 to depend from independent Claims 20, 39, and 66 respectively. For purposes of examination, the Examiner assumed the aforementioned amendments.

15

Upon a review of the claims, a dependency allowing for sufficient antecedent basis is as follows. Claims 37, 55, 70-72, and 73 have been amended to depend from Claims 30, 39, 66, and 72, respectively. Because these amendments are not considered to be narrowing and were therefore not made for statutory reasons of patentability, the 20 proposed amendments should not affect the doctrine of equivalents, as Festo should not apply. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 520 U.S. 1111 (1997).

Because Claims 37, 55, 70-72, and 73 now have proper antecedent basis, the 25 Applicant believes that the claims are no longer indefinite and therefore particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Thus, the Applicant respectfully requests that the Examiner withdraw this rejection.

C. **Claim Rejections – 35 U.S.C. §102**

The Examiner rejected Claims 1-4, 9-17, 58, 59, and 62-65 under 35 U.S.C. §102(b) as being anticipated by the Caron reference.

5 The Examiner stated the claims are drawn to a method of aligning gene expression data of exons to a chromosomal map, thereby creating an expression map. The Examiner also stated that in some embodiments, sets of co-expressed genes are identified, a plurality of expression data from different conditions are mapped to chromosomal positions, and an entire chromosome is mapped.

10 The Examiner further stated that the Caron reference details results from a complete human transcriptome map. The Examiner also stated that the Caron reference shows that SAGE expression data was used on page 1289 (which the Examiner contends is derived from processed eDNA transcripts, known in the art to consist of exons, as shown in page 3 of the supplemental material). The Examiner further stated that the Caron reference shows a portion of the complete transcriptome map in figure 1, which shows an expression map of human chromosome 11 in which the expression profiles of eight different cell types are indicated. The Examiner concluded by stating that the Caron reference notes the presence of regions of increased gene expression (termed RIDGEs) on page 1290-1292.

Addressing the requirements of anticipation, the Federal Circuit stated that, “There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” *Scripps Clinic & Research Found. v. Genentech Inc.*, 927 F.2d 1576 (Fed. Cir. 1991). Furthermore, the Federal Circuit stated that “Anticipation requires that every element of the claims appear in a single reference ...” *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991), and that “Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W.L. Gore & Associates v.*

Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). In addition, the Federal Circuit stated that under 35 U.S.C. § 102, “anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452 (Fed. Cir. 1984).

5 Therefore, in order to establish a prima facie case of anticipation the Examiner must set forth an argument that provides (1) a single reference (2) that teaches or enables (3) each of the claimed elements (as arranged in the claim) (4) either expressly or 10 inherently and (5) as interpreted by one of ordinary skill in the art. All of these factors must be present, or a case of anticipation is not met.

15 PLEASE NOTE: 1-4, 9-17, 58, 59, and 62-65 include both independent and dependent claims. More specifically, Claims 1 and 58 are independent claims, while Claims 2-4, 9- 17, 59, and 62-65 depend therefrom. For clarity, the independent claims will be addressed first, with the dependent claims thereafter being addressed.

Claims 1 and 58

Regarding Claims 1 and 58, the pertinent part of the Claims 1 and 58 have been 20 amended to read, “...associating the gene expression within the first gene expression pattern with its corresponding exon, the corresponding exon having a length such that the gene expression is associated with the entire length of the corresponding exon.” The present invention describes a method for analyzing gene expressions. The gene expressions are mapped by explicitly associating the gene expression with its 25 corresponding exon. Such association is not due to overlap or haphazard association, but rather is associated with the entire length of the corresponding exon. Thus, the present invention provides a fine-resolution mapping system.

The present invention is to be contrasted with the Caron reference, where the mapping is done at a more rough resolution. The Caron reference maps expression levels across the chromosome at the gene level, not the exon level. At its finest resolution, the Caron reference maps “expression levels …for…individual tags of a gene.” (See the 5 Caron reference, page 1290, column 3, lines 32-25). As illustrated by Figure 2 of the Caron reference, the mapping is to a marker comprising a 10 base pair region, not an exon.

In other word, at its finest resolution, the Caron reference maps expression levels 10 to a 10 base pair region. Although the marker may overlap an exon, the mapping is not associated with the entire length of the corresponding exon. Thus, the Caron reference does not teach or enable each limitation as set forth in Claims 1 and 58. Specifically, the Caron reference does not teach or enable “…associating the gene expression within the first gene expression pattern with its corresponding exon, the corresponding exon having 15 a length such that the gene expression is associated with the entire length of the corresponding exon” as is required by Claims 1 and 58.

Because the Caron reference does not teach or enable each limitation as set forth in Claims 1 and 58, the Applicant believes that these claims are now in allowable 20 condition. Thus, the Applicant respectfully requests that the Examiner withdraw this rejection of Claims 1 and 58.

Claims 2-4, 9-17, 59, and 62-65

Regarding Claims 2-4, 9-17, 59, and 62-65, the Applicant refers the Examiner to 25 the comments above regarding Claims 1 and 58. Because the Caron reference does not teach or enable each of the claimed elements of Claims 1 and 58, the Applicant believes that Claims 2-4, 9-17, 59, and 62-65, which depend therefrom, are also allowable. Thus, the Applicant respectfully submits that a case of anticipation has not been met. Therefore, the Applicant respectfully requests that the Examiner withdraw this rejection.

D. Claim Rejections – 35 U.S.C. §103

The Examiner rejected Claims 1, 2, 18-23, 28-42, 47-57, 66, 67, 70-75, and 78-81 rejected under 35 U.S.C. 103(a) as being unpatentable over the Caron reference in view 5 of Kanehisa et al. (hereinafter referred to as the “Kanehisa reference”).

The Examiner stated that the claims are drawn to a method of aligning gene expression data of exons to a chromosomal map thereby creating an expression map. The Examiner further stated that in some embodiments, sets of co-expressed genes are 10 identified, a plurality of expression data from different conditions are mapped to chromosomal positions, and an entire chromosome is mapped. The Examiner also stated that in some embodiments, the claims are drawn to computers and programs that execute the method. Additionally, the Examiner stated that in some embodiments, the maps are of different genomes.

15

The Examiner also stated that the Caron reference details results from a complete human transcriptome map. The Examiner further stated that the Caron reference shows that SAGE expression data was used on page 1289 (which the Examiner contends is derived from processed cDNA transcripts, known in the art to consist of exons, as shown 20 in page 3 of the supplemental material). The Examiner also stated that the Caron reference shows a portion of the complete transcriptome map in figure 1, which shows an expression map of human chromosome 11 in which the expression profiles of eight different cell types are indicated. The Examiner further stated that the Caron reference notes the presence of regions of increased gene expression (termed RIDGEs) on page 25 1290-1292. The Examiner also stated that the Caron reference details use of databases and algorithms to generate and analyze the data of their method of making a transcriptome map throughout the supplemental material pages 1-11.

However, the Examiner stated that the Caron reference does not explicitly show computers and programs that execute their method, nor does it show comparison of expression profiles of different genomes.

5 The Examiner continued by stating that the Kanehisa reference describes a knowledge base termed KEGG in the abstract and throughout that comprises genomic information including genomic maps and gene expression profiles. The Examiner also stated that the Kanehisa reference states on page 27 that their knowledge base uses computerized tools and software to facilitate the analysis depicted in figure 1. The
10 Examiner continued by stating that the Kanehisi reference shows on page 28 that their system comprises gene expression profiles that allow the user to detect co-regulated genes that are clustered on a chromosome. The Examiner further stated that Table 1 of the Kanehisi reference shows that KEGG has 23 complete genome maps and four sets of expression maps. The Examiner further stated that the Kanehisa reference shows
15 comparison of orthologs and genome-genome comparisons on page 29.

The Examiner concluded that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of generating expression map comparisons of the Caron reference by use of data of multiple genomes
20 because the Kanehisa reference shows databases and methods of comparing data of multiple genomes to compare orthologs. The Examiner further contends that it would have been further obvious to automate the procedures of the Caron reference because the Caron reference discusses use of programs and computer databases, while the Kanehisa reference shows that similar collections of expression maps can be analyzed by
25 computers and programs, and because automation of a manual activity is recognized as obvious, as noted in the MPEP at section 2144.04.

In order to establish a *prima facie* case of obviousness, the Examiner must set forth an argument that provides (1) one or more references (2) that were available to the

inventor and (3) that teach (4) a suggestion to combine or modify the references, (5) the combination or modification of which would appear to be sufficient to have made the claimed invention obvious to one of ordinary skill in the art. Importantly, the teaching or suggestion to make the claimed combination must be found in the prior art, not in
5 Appellant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

PLEASE NOTE: Claims 1, 2, 18-23, 28-42, 47-57, 66, 67, 70-75, and 78-81 include both independent and dependent claims. More specifically, Claims 1, 20, 39, 66, and 74 are independent claims, while Claims 2, 18, 19, 21-23, 28-38, 40-42, 47-57, 67, 70-73, 10 75, and 78-81 depend therefrom. For clarity, the independent claims will be addressed first, with the dependent claims thereafter being addressed.

Claims 1, 20, 39, 66, and 74

Regarding Claims 1, 20, 39, 66, and 74, the Applicant refers the Examiner to the discussion above regarding Claims 1 and 58. Similarly, Claims 1, 20, 39, 66, and 74 have been amended to include, in pertinent part, the limitation of "...associating the gene expression within the first gene expression pattern with its corresponding exon, the corresponding exon having a length such that the gene expression is associated with the entire length of the corresponding exon." As discussed above, the Caron reference does not teach associating the gene expression with the entire length of the corresponding exon. More specifically, the Caron reference teaches associating the gene expressions at the gene level. This is to be contrasted with the present invention, where the gene expressions are associated with the entire length of the corresponding exon.
20

Further, nowhere in the Kanehisa are any references to associating the gene expression with the entire length of the corresponding exon. Thus, combining the Kanehisa reference with the Caron reference does not teach, enable, or otherwise suggest each of the claimed limitations of Claims 1, 20, 39, 66, and 74. Therefore, because neither the Caron reference nor the Kanehisa reference, either alone or in combination,
25

teach each of the claimed limitations of Claims 1, 20, 39, 66, and 74, the Applicant respectfully requests that the Examiner withdraw this rejection.

Claims 2, 18, 19, 21-23, 28-38, 40-42, 47-57, 67, 70-73, 75, and 78-81

5 The Applicant refers the Examiner to the comments above regarding Claims 1, 20, 39, 66, and 74. Because neither the Caron reference nor the Kanehisa reference, either alone or in combination, teach each of the claimed limitations of Claims 1, 20, 39, 66, and 74, the Applicant believes that Claims 2, 18, 19, 21-23, 28-38, 40-42, 47-57, 67, 70-73, 75, and 78-81, which depend therefrom, are also allowable. Thus, the Applicant
10 respectfully requests that the Examiner withdraw this rejection.

E. Allowable Subject Matter

15 Claims 7, 8, 26, 27, 45, 46, 61, 69, and 77 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The Applicant directs the Examiner to the comments above regarding Claims 1, 20, 39, 58, 66, and 74. As discussed above, the Applicant believes that Claims 1, 20, 39, 58, 66, and 74 are in allowable condition. Therefore, because Claims 7, 8, 26, 27, 45, 46, 20 61, 69, and 77 depend from allowable base claims, the Applicant believes that these claims are also allowable. Therefore, the Applicant respectfully requests that the Examiner provide for timely allowance of all pending claims.

CONCLUSION

The Applicant respectfully submits that in light of the above amendment/remarks, all claims are now in allowable condition. The Applicant thus respectfully requests timely allowance of all of the pending claims.

5

Any claim amendments that are not specifically discussed in the above remarks are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments.

10 Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those skilled in the art to clearly understand the scope of the claim language. Furthermore, any new claims presented above are of course intended to avoid the prior art, but are not intended as replacements or substitutes of any cancelled claims. They are simply additional specific statements of inventive concepts described in the application as originally filed.

15

Further, it should be noted that amendment(s) to any claim is intended to comply with the requirements of the Office Action in order to elicit an early allowance, and is not intended to prejudice Applicant's rights or in any way to create an estoppel preventing Applicant from arguing allowability of the originally filed claim in further off-spring applications.

20

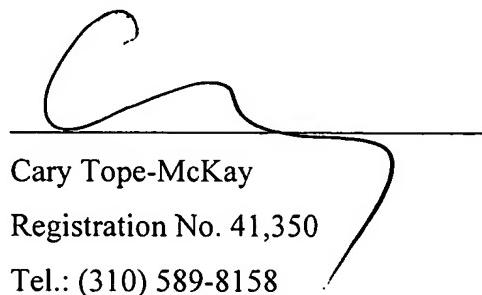
In the event the Examiner wishes to discuss any aspect of this response, or believes that a conversation with either Applicant or Applicant's representative would be beneficial, the Examiner is encouraged to contact the undersigned at the telephone number indicated below.

25

The Commissioner is authorized to charge any additional fees that may be required or credit overpayment to the attached credit card form. In particular, if this response is not timely filed, the Commissioner is authorized to treat this response as

including a petition to extend the time period pursuant to 37 CFR 1.136(a) requesting an extension of time of the number of months necessary to make this response timely filed. The petition fee due in connection therewith may be charged to deposit account no. 50-2738 if a credit card form has not been included with this correspondence, or if the credit
5 card could not be charged.

Respectfully submitted,



Cary Tope-McKay
Registration No. 41,350
Tel.: (310) 589-8158

10